

## REMARKS

Claims 1-3, 5 and 7-20 are pending in the instant application. Claims 1 and 15 have been amended. New claims 22-25 have been added. No new matter has been added.

### **I. Telephone Interview**

The Applicant would like to thank the Examiner for taking the time to review and discuss the proposed claim language and arguments with the Applicant on March 3, 2010. The Applicant appreciates that the Examiner indicates that the proposed amendment if combined properly with the further limitation of following a pattern of surface application appears to distinguish over the prior art.

### **II. Rejections under 35 USC §102**

Claims 1-3 and 7-20 stand rejected under §102(b) as being anticipated by Knowlton I (6,350,276).

#### **The prior art**

Knowlton I discloses "a monopolar RF energy system 26' current flows from RF energy source 22 to the RF electrode 18 also known as the active electrode 18, into the patient and then returns back to RF generator 22 via a second electrode 19 known as a passive electrode 19, return electrode 19, or ground pad 19 which is in electrical contact with the skin of the patient (e.g. the thigh or back)" (col. 15, lines 49-55, FIG. 18A). It also discloses "a bipolar RF energy system 26", individual RF electrodes 18 have positive and negative poles 29 and 29'. Current flows from the positive pole 29 of one electrode to its negative pole 29', or in a multiple electrode embodiment, from the positive pole 29 of one electrode to the negative pole 29' of an adjacent electrode" (col. 16, lines 54-59, FIG. 18B). Thus, both the monopolar and the bipolar RF energy systems as disclosed apply random heating to a large area of tissue via current 27 between the active electrode and the passive electrode as shown in FIGS. 18A-B.

Such random heating of skin in Knowlton I, however, cannot assure that a clinical effect, which requires specific pattern and depth, will occur. More specifically, heating of the skin (dermis) does not necessarily result in dimensional tightening of the skin's surface and certainly will not result in an effect that results in an aesthetically enhanced clinical effect. For example, a non-continuous heating of the skin would not necessarily

cause a 2 dimensional tightening of the skin's surface and certainly may not result in a 2 dimensional tightening of the skin surface in the correct direction to provide an enhanced clinical effect. In addition, heating of lipocytes does not necessarily cause a three-dimensional inward contouring of soft tissue. In fact, a three-dimensional outward contouring of soft tissue (trapdoor effect) can occur with improper heating of the lipocytes and fibrous septae. A controlled delivery of specific patterns of application of RF energy with the correct depth and thermal dose must be employed for skin tightening and inward contouring to occur with an enhanced clinical outcome, which Knowlton I did not disclose.

**The prior art distinguished**

In the Final Office Action mailed 11/13/2008, the Examiner suggested that "[i]f Applicant is attempting to claim an electromagnetic device which delivers RF energy having one particular pattern to one tissue depth and RF energy having a different particular pattern, then Applicant should explicitly do so" (page 7 of the instant final office action).

In the Interview Summary for the interview conducted on 03/03/2010, the Examiner further note that the "proposed amendment if combined properly (with the further limitation of following a pattern of surface application) appear to distinguish over the prior art."

According to the Examiner's suggestion, Applicant has amended claim 1 to include the language of:

delivering following a first pattern of surface application to deliver RF energy with controlled dose and depth to the tissue site at a first depth to achieve a first tissue effect; wherein the first tissue effect is a two dimensional tightening of the skin surface;  
delivering following a second pattern of surface application to deliver RF energy with controlled dose and depth to the tissue site at a second depth to achieve a second tissue effect; wherein the second tissue effect is a three dimensional tissue repositioning or inward contouring;

Claim 15 has been amended to include the language of:

delivering following a pattern of surface application to deliver RF energy with controlled dose and depth RF energy to the tissue site to achieve a tissue effect to correct the deformity using an energy delivery device

Such claim amendments are fully supported by at least the following paragraphs of the specification:

Following surface patterns of RF energy application

[0237] The creation of a thermal lesion for a desired therapeutic effect can be achieved by a number of means. In an embodiment, the creation of lesions can be facilitated by configuring energy delivery during a Thermage or other treatment to produce a delivered thermal dose that is both substantially uniform and of an amount that will result in a directed wound healing response capable of producing one or more of aesthetic contouring, tissue tightening or tissue reshaping. There are a variety of factors which may be considered in producing such a wound healing response. Such factors can include without limitation, the pattern of energy application, the pattern of force delivery and vectored pre-positioning of the tissue...

[0238] Referring now to FIGS. 41a-41f, a discussion will now be presented of various embodiments of energy delivery methods to produce selectable lesions 87l, or adhesion 87 and subsequent aesthetic outcomes, e.g., tissue re-contouring. In one embodiment, energy can be delivered using probe 112 to create a series of discrete or semi-discrete lesions 87l or adhesions 87 to produce a desired contour 9c. However, this approach may result in contour irregularities or discontinuities 9ci caused by untreated areas or margins 9ua between or adjacent treated areas 9ta. In other embodiments, this problem can be solved by the use of a pattern or series of overlapping energy applications 93 to grid sites 86. In these embodiments, energy delivery device 18 is used to perform a series of overlapping energy applications 93 to generate a substantially continuous and uniform lesion 87u comprised of one or more lesions 87l...

[0239] In one embodiment, a treatment algorithm uses energy delivery techniques described herein, wherein the appropriate treatment site is first selected with consideration given to avoidance of areas prone to unsightly complications. A grid pattern 86 is then marked or overlaid on the selected treatment site 9, the pattern

including individual grid sites 86s. A uniform thermal dose can then be produced using multiple energy applications or passes to a grid site 86s that overlaps the margins of the grid 86m to generate a continuous or uniform lesion 87u as described above. Each application can be configured to impart a thermal dose sufficient to generate an adhesion 87 or lesion 87l which can comprise part of lesion 87u...

#### Multiple energy treatments at different depths for different clinical outcomes

[0260] In various embodiments, the treatment plan can include a combination of energy treatments delivered to different tissue depths (e.g. more or less superficial). In these embodiments, both the dose and depth of energy delivery can be controlled (e.g., via control system 54 or other control means described herein). Referring back to FIG. 41e, in various embodiments energy can be delivered to different tissue depths 9td to achieve the same or different tissue effects at each depth. For example, energy can be delivered to a first tissue depth 9trf1 to achieve a first tissue effect and to a second depth 9td2 to achieve a second tissue effect. In one embodiment, one energy application energy can be delivered more superficially to the dermal tissue layers to achieve dermal contraction and two dimensional tightening of the skin surface. Then in subsequent energy applications, energy can be delivered deeper to the sub-dermal layers including one or more of the subcutaneous fat layer, fibrous septae, muscle fascia and muscle. Deeper energy deliveries can be configured to achieve one or more of the following tissue effects: i) thermal contraction of one more of the fibrous septae, fascia and muscle with three dimensional deep tissue repositioning of convex aesthetic deformities; and ii) thermal lipolysis with three dimensional inward contouring of convex aesthetic deformities.

#### Controlled dose and depth

[0261] In various embodiments, the depth and/or dose of energy delivery can be controlled by a number of means. These include, without limitation, control or selection of one or more of the following: RF frequency, power levels, pre-cooling periods, size of the electrodes, energy delivery time, use of mono-polar vs. bi-polar delivery (the former producing a deeper thermal effect) and tissue hydration levels (e.g., using infusion of conductive solutions). Deeper thermal deliveries can be achieved by increasing the size of the electrodes, increased power levels, increased energy delivery times (to allow

more time for thermal conduction), decreased rates of cooling, decreased pre-cooling periods (e.g. cooling prior to energy delivery) and decreased cooling periods.

As discussed above, Knowlton I does not disclose delivering multiple RF energy treatments following different patterns of surface application of RF energy with controlled dose and depth at the same tissue site as discussed above. Thus, Knowlton I cannot anticipate amended claims 1 and 15. Since the rest of the claims depend on claims 1 and 15, they are also allowable at least for depending from an allowable base claim. The Applicant respectfully requests all rejections with respect to these claims be withdrawn.

#### CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any fees, including fees for extension of time, or credit overpayment to Deposit Account No. 50-4634, referencing Attorney's Docket No. KNW-0019.

Respectfully submitted,  
GOODWIN PROCTER LLP

Date: 3-19-10

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